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Neil Polwart

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EXAMINER

YAM, STEPHEN K

ART UNIT

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2878

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/540,945 | POLWART, NEIL | |
| | Examiner | Art Unit | |
| | STEPHEN YAM | 2878 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/29/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 13, 17, 19, and 20 are objected to because of the following informalities:

In Claim 13, it is unclear whether Applicant intended to provide a "Markush" group, since Applicant uses open-ended language ("... selected from the group comprising") instead of closed-ended language for defining the group.

In Claims 17 and 19, the semi-colon at the end of the claim should be replaced with a period.

In Claim 19, line 2, "calibration" should be replaced with "the calibration" for proper antecedent basis.

In Claim 20, "the reference signal" lacks proper antecedent basis.

2. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 7-9, and 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Yee et al. US Patent No. 5,822,073

Regarding Claim 1, Yee et al. teach (see Fig. 11) a cartridge (61) for use in a Surface Plasmon Resonance sensor, the cartridge comprising an optical element (61) having a first

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surface (left) and a mounting member (69) for supporting a sensing agent (see Col. 15, lines 36-41 and Col. 19, lines 13-22) located on a second surface (66) of the optical element, the first surface comprising a first means (64) for directing a beam of light incident on the optical element towards the second surface at an angle of incidence to the second surface that results in substantially total internal reflection of the beam of light at an interface of the mounting member and the second surface (see Col. 3, lines 7-15) wherein the cartridge further comprises a detachable channel (70) (since the element is a static cell) suitable for containing a fluid sample to be tested (see Col. 15, lines 46-49).

Regarding Claim 2, Yee et al. teach the channel locates on the second surface of the cartridge such that the fluid sample contained within the channel makes physical contact with the sensing agent (see Fig. 11).

Regarding Claim 3, Yee et al. teach the optical element further comprises a third surface (63) for the exit of beam of light from the optical element wherein the third surface includes a second means (64) for directing the beam of light.

Regarding Claim 4, Yee et al. teach the optical element comprises a material having a first dielectric constant (dielectric constant of optical material which is positive) while the mounting member comprises a material having a second dielectric constant (see Col. 17, lines 18-22) wherein the second dielectric constant is of an opposite sign to that of the first dielectric constant (since metals and optical materials have opposite-sign dielectric constants).

Regarding Claim 7, Yee et al. teach the mounting member comprises a metal (see Col. 17, lines 18-22).

Regarding Claim 8, Yee et al. teach the optical element comprises a plastic material (see Col. 3, lines 61-64). Although Yee et al. does not specifically disclose the plastic material as injection moulded, such a limitation is directed towards a method of constructing the device and does not provide any additional structural limitations- since the claim is recited as a device claim, a specific method of manufacturing the device cannot be given patentable weight.

Regarding Claim 9, Yee et al. teach the sensing agent comprises one or more antibodies (see Col. 18, lines 29-30) each antibody being suitable for binding a pathogen (see Col. 18, lines 30-35).

Regarding Claim 14, Yee et al. teach a Surface Plasmon Resonance sensor comprising a light source (73) for generating a beam of light (see Fig. 11), a cartridge as claimed in claim 1 (see Fig. 11), and a light beam detection means (75) wherein the employment of the cartridge allows for the miniaturisation of the sensor (See Fig. 11).

Regarding Claim 15, Yee et al. teach the light source comprises a diode laser (see Col. 22, lines 25-28).

Regarding Claim 16, Yee et al. teach the light beam detection means comprises a detector (75) and a data processing means (inherent since processing must be required to analyze the raw detector data).

Regarding Claim 17, Yee et al. teach (see Fig. 11-14) a method of field detection of one or more pathogens that comprising the steps of: 1) Selecting an appropriate cartridge (61) for the detection of one or more pathogens for use in a Surface Plasmon Resonance sensor (see Col. 18, lines 22-42); 2) Calibrating the Surface Plasmon Resonance sensor (see Col. 19, lines 24-37);

and 3) Testing a fluid sample (see Col. 15, lines 46-49) for the presence of one or more of the pathogens (see Col. 18, lines 22-42).

Regarding Claim 18, Yee et al. teach the selection of the appropriate cartridge comprises locating the cartridge with one or more appropriate antibodies for binding with the one or more pathogens (see Col. 19, lines 13-22 - selecting the cartridge having the appropriate reactive layer).

Regarding Claim 19, Yee et al. teach the calibration of the Surface Plasmon Resonance sensor comprises: 1) Irradiating a mounting member with a beam of light in the absence of the fluid sample (see Col. 19, lines 34-46); and 2) Detecting a component of the beam of light reflected from the mounting member and storing the data as a reference signal (see Col. 19, lines 43-46, 60-66).

Regarding Claim 20, Yee et al. teach the testing of a fluid sample for the presence of one or more pathogens comprises: 1) Locating the fluid sample with respect to a channel (See Col. 19, lines 23-28); 2) Connecting the channel to the cartridge (see Fig. 11-14); 3) Irradiating the fluid sample with the beam of light (see Fig. 11); 4) Detecting the beam of light reflected from the mounting member and storing the data as a sample signal (see Fig. 11 and Col. 19, lines 27-30); and 5) Comparing the sample signal with a reference signal (see Col. 19, lines 27-30).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson et al. US Patent No. 6,717,663 in view of Yee et al.

Regarding Claim 1, Atkinson et al. teach (see Fig. 13-15) a cartridge (226) for use in a Surface Plasmon Resonance sensor, the cartridge comprising an optical element (226) having a first surface (left in Fig. 15) and a mounting member (holding (227)) located on a second surface (top in Fig. 15) of the optical element, the first surface comprising a first means (224) for directing a beam of light incident on the optical element towards the second surface at an angle of incidence to the second surface that results in substantially total internal reflection of the beam of light at an interface of the mounting member and the second surface (see Col. 1, lines 16-20) wherein the cartridge further comprises a detachable channel (227) suitable for containing a fluid sample (TS) to be tested (since the device is a biosensor). Atkinson et al. do not teach the mounting member supporting a sensing agent. Yee et al. teach (see Fig. 11) a similar device with a mounting member (side mounts to the left and right of (68), (69)) for supporting a sensing agent (see Col. 15, lines 36-41 and Col. 19, lines 13-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mounting member supporting a sensing agent, as taught by Yee et al., in the device of Atkinson et al., to provide reactions with the sample for improved sensitivity to a desired test condition.

Regarding Claim 3, Atkinson et al. teach the optical element further comprises a third surface (right in Fig. 15) for the exit of beam of light from the optical element wherein the third surface includes a second means (242A, 242B) for directing the beam of light (see Fig. 13).

Regarding Claim 5, Atkinson et al. teach the first means for directing the light beam comprises a focusing element for focusing the beam of light to a line at the interface of the mounting member and the second surface (see Col. 8, lines 3-6, 10-12).

Regarding Claim 6, Atkinson et al. teach the second means for directing the light beam comprises a defocusing element (see Fig. 13).

7. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yee et al.

Regarding Claims 10-13, Yee et al. teach the device in Claim 1, according to the appropriate paragraph above. Yee et al. do not teach the bound pathogen is selected from the group comprising Legionella, Escherichia coli, Salmonella, Bacillus Anthracis, Yersinia Pestis, Lysteria, Cryptosporidium, Variola virus, Picomaviridae Aphovirus, Filoviruses, any plasticiser, steroid, medicinal drug or illicit substance or any other known fluid borne bacterium, or wherein a protein substrate and a ligand is employed to bind a biotinylated antibody to the metal, wherein the protein substrate comprises biotin, wherein the ligand comprises a protein selected from the group comprising avidin, strepavidin and neutravidin. It is well known in the art to use biosensors for detecting a variety of desired substances, pathogens, or other biological features and to use and select from a variety of commercially available sensing agents, depending on the desired characteristic to be detected, the desired cost limitations, and the availability of the commercial market. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the binding of the particular claimed bound pathogens, and the combination of biotin and avidin/strepavidin/neutravidin, in the device of Yee et al., to use

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commercially available binding agents for improved performance of sensing a biological material.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rassman et al. US 6,833,920 and Bryne et al. US 6,734,956 teach similar surface plasmon resonance sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN YAM whose telephone number is (571)272-2449. The examiner can normally be reached on Monday-Friday 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on (571)272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen Yam/
Primary Examiner, Art Unit 2878